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QUALITY ASSURANCE PLAN

The Hazardous Material Packaging Transportation Safety Quality Assurance Program managed by the Associate Director of Plant Operations is designed to meet LLNL requirements as well as those of our Sponsor and the applicable Regulatory Agencies.

The plan described herein is designed to assure that activities, such as the packaging and transportation of hazardous materials, substances, and waste, procurement, inspection, usage, maintenance, and test, are conducted in a prescribed manner. The objective of this Quality Assurance program is to provide for the establishment, control and verification of the necessary performance of these activities appropriate to the risk associated and in compliance with jurisdictional and ES&H requirements.

Line management is responsible for the achievement of this objective and for the documentation and implementation of this Quality Assurance Plan. Each employee is responsible for the quality of his/her own work.

This document interprets the requirements and application of DOE Order 5700.6C for the HMPTS Program at the Laboratory.

Original signed and on file in the HMPTS Assurance Office

Dennis K. Fisher, Associate Director
Plant Operations

Hazardous Material Packaging & Transport Safety (HMPTS) Committee Charter

The Hazardous Material Packaging and Transportation Safety Committee has been established to address serious concerns noted by the 1990 Department of Energy Tiger Team assessment of the Laboratory.

Purpose The primary purpose of the Committee is to ensure full coordination, integration, and oversight of the three separate organizations which are charged with packaging and transporting hazardous materials, substances and wastes. The three organizations charged with this responsibility are the Materials Management Section, Applied Engineering Division; the Materials Distribution Division, of the Office of Procurement and Material Manager, and the Hazardous Waste Management Division, Environmental Protection Department. The Committee will also assess the effectiveness of the Laboratory's overall hazardous material packaging and transportation safety program. The Associate Director for Plant Operations oversees the effectiveness of the Committee's activities.

Responsibilities The Committee:

1. Coordinates internal and external appraisals of all hazardous material packaging and transportation operations, and tracks and assesses the effectiveness of any corrective actions taken to address identified concerns or deficiencies.
2. Oversees the preparation of a formal on-site hazardous material packaging and transportation operations, and tracks and assesses the effectiveness of any corrective actions taken to address identified concerns or deficiencies.
3. Develop and issues the HMPTS Quality Assurance Plan and HMPTS procedures relating to hazardous materials packaging transportation safety, and reviews and ensures full coordination of the individual Quality Assurance plans within the three involved organizations.
4. Addresses institutional concerns involving packaging and transportation of hazardous materials, substances and wastes.

Membership The Committee is chaired on a rotational basis by a department head or a senior management person from the three involved departments. The Committee Chair is assisted by a full-time Assurance Officer matrixed from the Plant Operations Assurance Office. Membership is comprised of the Section Leader from Materials Management; Division Leaders, Hazardous Waste Management and Materials Distribution and also includes the Hazards Control Department, the Laboratory Traffic Manager, and a Site 300 Representative.

Meetings The Committee meets once a month, or more often if needed, to fulfill its responsibilities.

(Charter Signed and Approved by Dennis K. Fisher, Associate Director, Plant Operations and is on file in the HMPTS QA office.)

1.0 Introduction

The Associate Director of Plant Operations has established the Hazardous Materials Packaging and Transportation Safety (HMPTS) Committee. The Committee is chartered to assure that hazardous materials, hazardous substances, and hazardous wastes are properly and safely packaged and handled at the LLNL Facility.

This Quality Assurance Plan is published, distributed and maintained by the Lawrence Livermore National Laboratory Hazardous Packaging and Transportation Safety Committee and HMPTS Chairperson.

1.1 Policy

It is the policy of the HMPTS Committee that all work contributing to the operational objectives defined in its charter be performed to a level of quality that is appropriate to these objectives. Such quality levels are to be consistent with and supportive of operational performance, schedule, criticality, risk, and cost constraints. This policy shall:

- Satisfy applicable Federal, State, local, and other regulations and requirements, and consideration of Environment, Safety, and Health , and Quality concerns.
- Protect the health and safety of employees, subcontractors, and the general public.
- Provide protection for the hazardous materials, hazardous substances, and hazardous wastes being transported.
- Prevent release of such hazardous materials, hazardous substances, and hazardous wastes into the environment.
- Assure that management controls applied to HMPTS activities are adequate to assure validity, integrity, and reliability of the work performed as directed by DOE Orders
- Complement all LLNL ES&H requirements.
- Assure that Motor Carrier Operations are carried out in a manner that meets the intent of the applicable Federal Motor Carrier Regulations including the Drivers Qualification Files.

2.0 Purpose and Objectives

This Quality Assurance Plan (QAP) establishes a system of policy, authority, organization, responsibility, requirement, and documentation necessary to obtain the level of quality stated in the policy and to control certain LLNL Packaging and Transportation (P&T) activities. Specifically, these activities apply to P&T for off-site shipments and on-site transfers of hazardous materials, hazardous substances, hazardous wastes, and for Motor Carrier Operations which are defined by applicable Federal, State, and other regulations and requirements.

3.0 Scope

The QAP shall be binding on all personnel representing the Principal Members and General Members organizations as identified in section 5.1. It is also binding on those having responsibility for planning and scheduling HMPTS operations.

The Department of Transportation (DOT), Department of Energy (DOE) and Nuclear Regulatory Commission (NRC), along with international agencies, have established and coordinated requirements and regulations for container and packaging integrity as well as approved methods for moving, transfer, and shipping hazardous materials, hazardous substances, and hazardous wastes. The packaging and transportation of hazardous materials, hazardous substances, hazardous waste will be accomplished in accordance with all applicable regulations.

LLNL P&T operations are not particularly large in terms of number of shipments made, but the diversity, uniqueness, potential health risk, environmental risk, and potential damage and loss of valuable materials could result in unnecessary programmatic cost expenditures, if not properly controlled.

4.0 Compliance and Applicability

The basic requirements of the HMPTS Quality Assurance program are the Quality Assurance Criteria listed as follows, which are HMPTS's interpretation of the applicable elements of the 10 Criteria of DOE Order 5700.6C, Quality Assurance and its guidelines.

The HMPTS Chairperson does not interpret DOE Order 5700.6C as requiring the development of duplicate or redundant management systems when the requirements of DOE Orders other than 5700.6C can be served to meet the requirements of one or more of the 10 HMPTS QA Criteria .

The HMPTS Committee Chairperson requires the principal members management to implement this QAP using guidance found in Procedure QP 1.1. However, management should use a graded approach to implementation based on the scale, cost, complexity, hazards, and programmatic significance of the work performed as defined by the HMPTS Hazard/Assurance Prioritization found in Appendix B.

This QAP and QA Procedures are distributed and maintained on a controlled-copy basis. Holders of controlled copies of this plan and its procedures will receive copies of new or revised plans and procedures as they are issued with notices to remove deleted materials.

5.0 Quality Assurance Criteria

5.1 Program Responsibility, Authority and Organization — Criterion 1

The HMPTS Committee has been permanently established to assure full coordination, integration, and oversight of the three separate organizations which are charged with packaging and transporting hazardous materials, hazardous substances, and hazardous wastes. The three organizations charged with this responsibility are designated as Principal Members, Hazardous Waste Management Division, Material Distribution Division, and the Materials Management Section. See Figure 1-1.

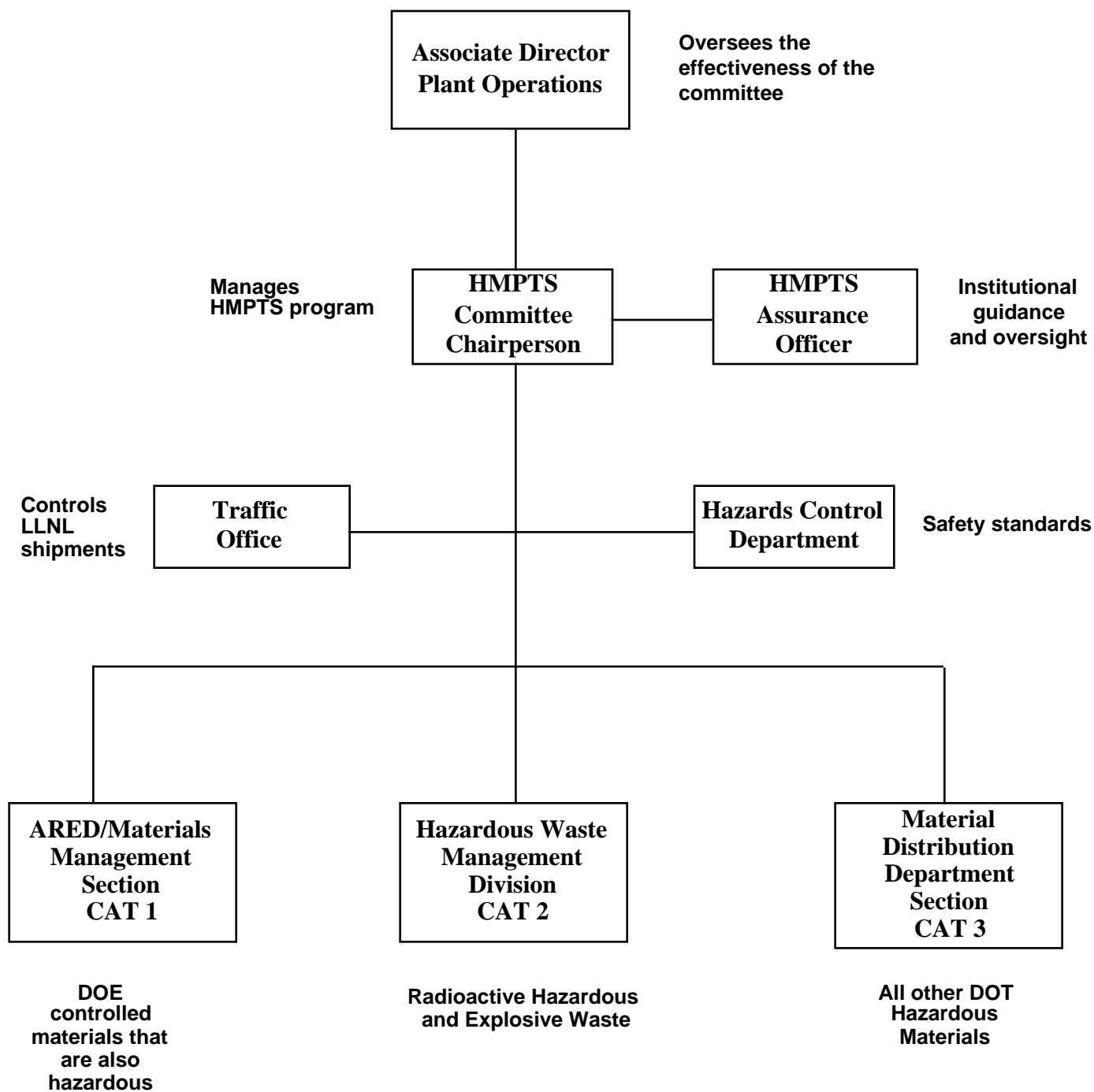


Figure 1-1. Functional responsibilities of the HMPT Safety Committee.

The Committee shall:

- Oversee the preparation of a formal on-site Hazardous Materials Packaging and Transportation Safety program, and effect the coordination and implementation of this program throughout the Laboratory.
- Oversee the revision of this Quality Assurance Plan relating to hazardous materials, hazardous substances, and hazardous wastes packaging and transportation, and assure full coordination and implementation of the subordinate Quality Assurance Plans within the three Principal Member organizations.
- Initiate internal and external compliance and safety appraisals of all hazardous materials, hazardous substances, and hazardous wastes packaging and transportation operations, and track and assess the effectiveness of any corrective actions taken to address identified concerns or deficiencies.

There are other participating organizations and members in the committee which have responsibility for performing and conducting activities contributing to various phases of hazardous materials, hazardous substances, and hazardous wastes packaging and transportation work. They are also members of the Committee and are designated below as General Members.

5.1.1 Principal Members

Principal Members shall have the authority to stop any phase of the HMPTS operation when an unsafe condition or a situation detrimental to container quality or transportation quality has been identified.

Principal Members include:

- Materials Management Section (MMS)
- Hazardous Waste Management Division (HWM)
- Material Distribution Department (MDD)

5.1.2 General Members

LLNL groups that purchase, fabricate, maintain, or otherwise support the HMPTS Program shall do so in accordance with this HMPTS QAP. The scope of their work may be performed in accordance with a QA Plan or with other organizational procedures.

General Members include representatives from the following areas, as well as others not listed who participate on an as needed basis:

- Hazard Control Department
- Traffic Office
- Procurement
- Environmental Protection Department/Waste Certification Program Manager

- Business Services Department
- Plant Engineering Department
- Site 300 Management Representative

5.1.3 Management Actions and Responsibilities

To promote the efficient actions necessary for achievement of the HMPTS performance objectives, the Line Managers (senior managers and department heads) who are responsible for assuring HMPTS Program committee member participation and compliance by their organizations shall:

- Provide adequate resources for the required HMPTS Program activities by their groups.
- Assure that HMPTS Program required QA Plans are prepared, maintained, and implemented.
- Assure that transfer services provided by Principal Members are appropriately used.
- Assure that work is assigned such that planning and schedule considerations are independent and do not override safety considerations.
- Assure that planning estimates are based on historical data and good business practices relating to personnel, material/service costs, availability, and productivity.

5.1.4 Requirements Compliance

To assure continued compliance with jurisdictional requirements, Principal Members identify necessary changes to their Specific QAPs as required. These include:

- Incorporate changes to the HMPTS QAP, QA procedures, and their own Specific Quality Assurance (SQAPs) to fully and correctly respond to new requirements.
- Establish and implement procedures to ensure compliance with applicable requirements for:
 - 1) containers for hazardous materials, hazardous substances, and hazardous wastes;
 - 2) packaging methods for hazardous materials, hazardous substances, and hazardous wastes;
 - 3) transfer methods for movement of hazardous materials, hazardous substances, and hazardous wastes on-site;
 - 4) transportation and shipping methods for hazardous materials, hazardous substances, and hazardous wastes destined for off-site shipment, and
 - 5) maintenance, inspection, and recertification of Type B packaging and industrial gas cylinders/vessels.

5.1.5 Functional Responsibilities

Organizational interface and structure of the HMPTS Committee is shown in Figure. 1-2. Functional and coordinating responsibilities for these organizations is described as follows.

5.1.5.1 Associate Director, LLNL Plant Operations

The Associate Director for Plant Operations has line responsibility for directing the HMPTS Program, and shall:

- Oversee and monitor the effectiveness of the Committee's activities by reviewing the HMPTS committee's minutes for audit findings and their implemented corrective actions.
- Approve and sign the HMPTS QAP and any revisions.
- Assure necessary resources are provided to implement the HMPTS Program, as reflected in program budgets.
- Appoint assignment of the HMPTS Committee Chairperson.

5.1.5.2 The HMPTS Committee Chairperson

The Committee is chaired on approximately a two year rotational basis by a Department Head or a Senior Management Person from the three Principle Members.

The HMPTS Committee Chairperson is matrixed to the Associate Director of LLNL Plant Operations and shall:

- Keep the Associate Director for Plant Operations apprised of the state of the HMPTS Program, through issuance of minutes and action items resulting from the monthly meetings.
- Initiate review and approval of the HMPTS QAP and QA Procedure activities.
- Establish and maintain an approved controlled-copy distribution list for the QAP and QA Procedures with revisions and also for the On-site Hazardous Materials Packaging and Transportation Safety Manual and revisions, see Ref. 2. Uncontrolled copies may be provided for information only.
- Review and approve for issue the QAP and QA procedures, and Principal Participant's Quality Assurance Plans and revisions which disclose HMPTS Program activities.
- Schedule regular monthly HMPTS Committee meetings, or more often if necessary, to assure full coordination, integration, and oversight of the Committee objectives.
- Review and approve the On-site Packaging and Transportation Safety Manual.

5.1.5.4 HMPTS Assurance Officer

The HMPTS Assurance Officer (AO) reports to the Deputy Associate Director for Technology Planning & Assurance in Plant Operations. The AO is matrixed to the HMPTS Committee Chairperson on permanent assignment to the committee, and shall:

- Indicate concurrence by signing the HMPTS QAP and On-Site Manual.
- Coordinate container procurement for LLNL Organizations on matters concerning hazardous materials, hazardous substances, and hazardous wastes.
- Coordinate HMPTS container procurement activities.
- Review technical requirements for HMPTS container procurement.
- Coordinate nonstandard container purchases.
- Coordinate institutional HMPTS concerns.
- Coordinate internal and external assessments of the HMPTS Program.
- Coordinate institutional Motor Carrier Operations concerns.

5.1.5.5 HMPTS Certification Management Officer

The HMPTS Certification Management Officer (CMO) reports to the HMPTS Assurance Officer and assists in the implementation of the Quality Assurance aspects for the HMPTS Program. The CMO and shall:

- Coordinate LLNL organizations on matters concerning HMPTS Quality Assurance.
- Assure that quality and documentation requirements for HMPTS container procurement are included in the purchase order, when necessary.
- Survey potential suppliers as identified by Procurement and the HMPTS Assurance Office.
- Establish and maintain a list of qualified container suppliers.
- Monitor the results of inspection and vendor evaluations, as documented on Nonconformance and Assessment Reports.
- Maintain Record copies of HMPTS quality assurance and container procurement records.
- Approve completed HMPTS Non Conformance Reports (NCRs).
- Review corrective action and track deficiencies.
- Approve and verify effectiveness of corrective actions.
- Maintain this HMPTS QA Plan and associated QA Procedures.

5.1.6 Principal Members

5.1.6.1 Materials Management Section

Materials Management Section (MMS) reports to the Applied Research Engineering Division (ARED). The MMS Section Leader is a Principal Participant responsible for shipping hazardous materials, hazardous substances, and related activities including:

- Packaging of Category I hazardous materials for movement on-site and off-site.
- Providing transportation per established practice and as requested for controlled materials that are also hazardous materials.
- Serving as the LLNL interface with the DOE for DOE-furnished shipments of nuclear components and special assemblies and high explosives.
- New explosive shipping classification.
- DOT exemptions.
- Maintain adequate storage for empty and loaded packages
- Maintenance and certification of Type B containers.

5.1.6.2 Hazardous Waste Management Division

Hazardous Waste Management (HWM) Division reports to the Environmental Protection Department (EPD). The HWM Division Leader is a Principal Participant and provides packaging and shipping of hazardous wastes activity including:

- Collecting waste from waste accumulation area(s).
- Packaging Category II hazardous materials, radioactive materials, and mixed waste for shipment.
- Releasing Loaded Containers to the Traffic Manager for shipping.
- Interfacing with the Federal, State, and other agencies on hazardous waste issues.
- Administering the TRU and LLW Waste Certification Program.

5.1.6.3 Material Distribution Division

Material Distribution Division (MDD) reports directly to the LLNL Procurement and Material Manager. The MDD Division Leader is a HMPTS Principle Member and is responsible for HMPTS activities including:

- Packaging, shipping, and the transfer of Category III hazardous materials.
- Control all LLNL shipments of hazardous materials, hazardous substances, and hazardous wastes via commercial carriers.

- Provide LLNL HMPTS interface with jurisdictional authorities and commercial carriers in the off-site shipment of hazardous materials, hazardous substances, and hazardous wastes.
- Provide selection of the carrier and route for the shipment.
- Provide secondary oversight for DOT compliance of shipping papers, shipping containers, and carrier vehicle prior to shipment.
- Provide and maintain LLNL shipping records.
- Assure that deficiencies are documented on Nonconformance Reports, and that rejected containers are returned to suppliers with request for corrective action.

5.1.6.4 Principal Members Leaders

The Principal Members Leaders shall:

- Indicate concurrence by signing the HMPTS QAP, which includes the QA Procedures, and the on-site manuals.
- Perform HMPTS Program work in accordance with a QA Plan and QA procedures.
- Monitor activities related to assigned categories of the hazardous materials, hazardous substances, and hazardous wastes and submit the changes necessary to bring the HMPTS QAP into compliance with Federal, State, and other regulations and requirements changes during the QAP review process.
- Advise and provide guidance to HMPTS Committee members for obtaining technical assistance on regulatory requirements for container design and design reviews.
- Initiate procurement, and fabrication of containers when appropriate.
- Verify the use of containers which are designed and approved for the category of material to be shipped.
- Perform container receiving inspections.
- Train personnel in the requirements of the HMPTS Program.
- Provide approved disposition for NCRs, including corrective actions, on items under the operating organization's control.
- Assure that new and revised procedures for packaging and movement of hazardous materials, hazardous substances, and hazardous wastes are reviewed by the appropriate division leader or his designated representative.

5.1.7 General Members

5.1.7.1 Hazards Control Department

The mission of the Hazards Control Department in Plant Operations is to function as a leader to integrate the minimization of risk and the control of workplace hazards into the thoughts, plans,

and actions of Laboratory management and employees. The Department shall participate and support the HMPTS Committee activities for developing and maintaining standards of safety for packaging and transportation of hazardous materials, hazardous substances, and hazardous wastes, and for providing guidance in related HMPTS activities.

The Department Management Representative shall:

- Indicate concurrence by signing the HMPTS QAP and QA procedures.
- Monitor activities related to packaging and transfer operations for compliance with occupational ES&H regulations.
- Coordinate HMPTS concerns with applicable divisions within the Hazards Control Department.

5.1.7.2 Procurement

The Procurement representative provides support to the HMPTS Committee.

The Procurement representative shall:

- Identify potential container suppliers.
- May participate in supplier reviews and supplier Quality Assurance audits.
- Assure that containers for hazardous materials, hazardous substances, and hazardous wastes are procured from suppliers who have been evaluated and qualified under the HMPTS Quality Assurance Plan.

5.1.7.3 Laboratory Traffic Manager

The Laboratory Traffic Manager reports to the MDD Division Leader. The Traffic Manager is assigned to the HMPTS Committee, and has “go/no-go” authority for off-site shipments of hazardous materials, hazardous substances, and hazardous wastes.

The Laboratory Traffic Manager shall:

- Control all LLNL shipments of hazardous materials, hazardous substances, and hazardous wastes via common carrier.
- Provide LLNL HMPTS interface with jurisdictional authorities and commercial carriers in the off-site shipment of hazardous materials, hazardous substances, and hazardous wastes.
- Provide selection of the carrier and routing of shipment as appropriate
- Provide secondary oversight for DOT compliance of shipping papers, shipping containers, and carrier vehicle prior to shipment..
- Provide and maintain LLNL shipping records..

5.1.7.4 Waste Certification Program Manager

The Waste Certification Program Manager is responsible for certifying LLNL hazardous waste for off-site disposal. The Waste Certification Program Manager shall:

- Manage the LLNL TRU Waste Certification Program.
- Manages the LLNL Low Level Waste Certification Program.
- Provide technical guidance in packaging of certified waste forms.

5.1.7.5 Plant Engineering

- Provide qualified Commercial Licensed drivers for operation of plant owned commercial motor vehicles as part of normal plant maintenance operations.

5.1.7.6 Business Services Department

- Establish and maintain Driver Qualification Files for LLNL licensed commercial drivers.

5.1.7.7 Site 300 Management Representative

Represent the Site 300 Manager for all HMPTS related activities.

5.1.8 Key Terminology

Definitions as used throughout this HMPTS QAP and the HMPTS Program in general are provided in Appendix A.

5.2 Personnel Training and Qualification — Criterion 2

5.2.1 Training Requirements for Work Tasks

Personnel requirements and certifications are established and documented in the Principal Participant's formal training plan or implementing procedure, ensuring that personnel have proper qualification and training for performing the various critical or specialized HMPTS work. There is also an ongoing review of training needs and improvements by the Training Officer. The supervisor is advised by the Training Officer of the individual's training and retraining needs.

QA procedures take advantage of established Facility Safety Plans(s) (FSPs) to avoid duplication.

5.2.2 P&T Training Scope

Training of HMPTS personnel, by qualified instructors, includes both education in basic hazardous materials principles and the development of packaging and transportation skills and practices. Basic principals include training in criticality safety, radiation safety, and where applicable, regulations for packaging and handling of radioactive materials and hazardous materials, hazardous substances, and hazardous wastes.

On-the-job training is included in the HMPTS Program to place emphasis on correct performance of work, address potential consequences of improper work, and provide an understanding of why quality requirements exist.

5.2.3 Specialized Training

Management personnel responsible for HMPTS hazardous materials, hazardous substances, and hazardous wastes, packaging and transportation activity receive specialized training. This training may include, but is not limited to, DOT, OSHA, EPA, and DOE hazardous material and transportation workshops.

Personnel performing HMPTS packaging and transportation work that requires special skills or abilities are qualified prior to performing work. Qualification includes periodic demonstration of proficiency for each candidate to maintain skills and meet current practices and to strive for progressive improvement. This demonstration is monitored by the responsible line manager. The records of training are maintained in the Laboratory Repository of Completed Courses (LROCC).

Use of the DOE/HQ developed computer based training (CBT) by HMPTS Member Organizations, in order to meet the required Department of Transportation (DOT) training requirements in 49 CFR Subpart H-Training, shall be presented by individuals that are qualified to present the material.

Documented results for proof of DOT specific Hazardous Material Training is the responsibility of the specific organization which employs the DOT Hazmat employee. Additional collection of information which reference the type of training completed, dates of completion, and recurring training requirements, may be maintained in the LLNL's computerized (LROCC) database.

5.2.4 Retraining

Retraining frequencies to maintain proficiency and foster improvement are identified in the applicable training course requirements and the LLNL Training Program Manual. See Ref. 7.

5.3 Quality Improvement — Criterion 3

To assure that proper focus is given, that adequate resources are allocated, and that difficult issues are resolved, management is involved in the HMPTS quality improvement process by the review of the quality status report presented at the monthly HMPTS committee meeting.

Operating, Handling and Quality Assurance procedures and instructions are developed and implemented to prevent problems, promote safety, and reduce errors. Quality improvements are promoted through opportunities for improvement in regular audits, trend evaluations where appropriate, and effective use of corrective actions. In addition management at all levels should use “lessons learned” to improve performance and strive to eliminate ineffective management systems.

Management is required to foster a “no fault” attitude where all personnel are encouraged to identify and report performance problems to the appropriate level of management and where appropriate corrective action will be taken by management.

5.3.1 Quality Trends

Quality performance data is evaluated through the review of nonconformance and corrective action data, and other quality-related information such as receiving inspection. Results are analyzed by the Certification Management Officer to identify trends that adversely impact quality and to identify opportunities to improve items and processes. The Certification Management Officer reports the results of his analysis and presents them to the HMPTS committee, as needed for continuous improvement, at the monthly meeting for review and action by the committee.

5.3.2 Control and Reporting of Nonconformance Items

Items and processes in the HMPTS Program that do not conform to established requirements or that could lead to unacceptable conditions are promptly identified, documented, analyzed, resolved, and removed from inadvertent use in accordance with the HMPTS Nonconformance Reporting Procedure or the Principal Members Nonconformance Reporting System. The extent of a cause analyses for nonconformance items and processes shall be commensurate with the importance or significance of the problem as determined by the HMPTS Assurance Office or Principal Members QA representative. The disposition of nonconformances and approval of corrective actions is performed by the HMPTS Assurance Office or the QA representative of the affected discipline.

HMPTS occurrences investigations are decided in the Health and Safety Supplement 4.08, Incident Analysis Manual. Reporting is discussed by DOE Order 232.1 "Occurrence Reporting and Processing of Operations Information." Specific reporting is documented in the LLNL Implementation Procedure for this DOE Order.

5.4 Documents and Records — Criterion 4

HMPTS Committee Members management produce documentation that describes their organizations, functions, policies, decisions, equipment, procedures, and essential transactions at a level of detail that is commensurate with the scale, cost, complexity, hazards, and programmatic significance of the work being done. As required by DOE Order 1324.2A (Records Disposition), DOE Order 1324.5 (Records Management Program) and Title 44 U.S.C. Chapter 35 Paperwork Reduction Act of 1980, "...the objective should be to minimize the paperwork and record keeping burden within DOE and its contractors, minimizes cost of document and records management and maximize the usefulness of DOE and contractor records."

5.4.1 QA Plans and Procedures

The HMPTS Committee is responsible for writing, approving, and issuing this HMPTS QAP and implementing QA Procedures and the On-Site HMPTS Manual, and for reviewing the Principal Members Specific Quality Assurance Plans (SQAP) to assure consistency with requirements. The Committee is also responsible for conducting a periodic review of these plans and procedures. The cover sheet of this QAP and QA procedures shall be signed by the individuals representing the principal members, the chairperson and the Associate Director for Plant Operations signifying approval. The individual QA procedures, work instructions, and check lists identify the specific QA records to be maintained and stored and are signed and approved by the HMPTS Committee Chairman.

5.4.1.1 Principal Participant QA Plans

The Principal Members SQAP include HMPTS Program requirements within their respective QA plans. The HMPTS Committee Chairperson assures that the HMPTS requirements are properly incorporated into their QA plans and indicate concurrence by signing them.

5.4.1.2 Revisions

Revisions to the HMPTS QAP, QA procedures, On-Site HMPTS Manual, and Principal Participant's SQAPs, are prepared and approved by the organization that originally reviewed and approved the documents. Revisions are reviewed for technical content, feasibility of requirements and safety.

5.4.1.3 Distribution

HMPTS QAP, QA procedures, On-Site HMPTS Manual, and Principal Participant's SQAPs are controlled documents. Line management assures that the latest revision(s) are distributed and used by personnel performing HMPTS work.

Controlled copies of the approved HMPTS QAP, QA Procedures implementing HMPTS Program requirements, are so marked and numbered. Distribution shall include a receipt to be signed, dated and returned as directed on the receipt. Controlled copies are kept up-to-date by distribution of approved revisions. A Distribution Log is maintained showing the status of the distributions and returned receipts. The Distribution Log shall be maintained by the HMPTS Assurance Office.

NOTE: – *Uncontrolled, informal copies of the HMPTS QAP or QA Procedures may be distributed for information and shall be marked accordingly.*

Distribution of HMPTS QAP, QA Procedures includes HMPTS Committee members and Senior line managers participating in the HMPTS Program.

5.4.2 Operational Documents

Operational documents such as data files, specifications, purchase orders and related documents, vendor-supplied documents, supplier survey results, procedures, work instructions, operator aids, assessment, QA records, and data sheets are controlled in accordance with the methods as described in the applicable procedures.

5.4.3 Superseded Documents

Control of superseded and canceled HMPTS Program documents include measures to assure that only correct documents are in use. It is the responsibility of the line manager to assure that superseded and canceled documents are so marked. It is the individuals responsibility to assure proper filing and usage of the applicable revised document.

5.4.4 Records

5.4.4.1 General Record Process

The maintenance of records shall include provisions for retention, protection, preservation, legibility, traceability, accountability, and retrievability. All records shall be accessible for appraisal by internal and external organizations having the need to review them.

Members in the HMPTS Program who use or purchase containers for hazardous materials, hazardous substances, and hazardous wastes and ship off-site, or transfer on-site, shall develop a record process, and assure that the appropriate records, retention periods, and custodians are properly identified.

The HMPTS Assurance Office is the repository for all HMPTS generated Quality Records which include, Supplier Assessments, Receiving Inspection Check Lists, Nonconformance and Corrective Action Reports.

5.4.4.2 Special Record Processes

The HMPTS Program uses the Laboratory's personnel training record retention system for training records. The main components of this system is the LROCC (Laboratory Repository of Completed Courses) which is the record of completed training.

Additionally, TRAQ (Training Requirements and Qualifications) may be used. This is a Laboratory data base to determine the status of the training requirements of an employee, based on the employee's job assignment and work location. Retraining, which is required to be repeated at specific intervals, is noted in this system and it gives the line manager visibility in advance of the requirement.

5.4.4.3 Archive and Active Record Storage

HMPTS active records, less than a year old, are readily retrievable, that is within hours. Archive records, records from previous years, are stored in a manner that assures retrievability within a reasonable time period. All records are stored and dispositioned made in accordance with Laboratory requirements.

5.4.4.4 Driver's Qualification File

The Driver's Qualification Files for all LLNL employees whose job requires them to possess a Commercial Driver's License will be maintained by the Business Services Department. The HMPTS Assurance Officer is responsible for assuring that employees, new hires, and employees do not have any restrictions on their commercial driver's license that may prohibit them from driving a commercial motor vehicle. The Driver's Qualification Files Policy is in Appendix G of this QAP. The Driver Qualification File Procedure is found in Appendix J, QP-10.1.

5.5 Work Processes — Criteria 5

5.5.1 Quality Responsibility

The HMPTS Committee requires management at all levels to strive to maintain an efficient and effective work force and to appropriately utilize personnel skills in the assignment and quality of work responsibilities.

The individual worker is the first line in insuring quality, but line management is primarily responsible for ensuring that people who are assigned to tasks have the appropriate skills, experience, qualifications, certifications as required, equipment, instrumentation and materials necessary to carry out the work. When work is sufficiently complex or involves sufficient hazards as determined by responsible management, written procedures and criteria defining acceptable work performance and objectives shall be specified.

HMPTS QAP and QA Procedures and Principal Participant's SQAP and Procedures are the guides for defining the required work processes for the HMPTS Program. The responsibility for the quality of the work performed by the HMPTS principal member groups belongs to the individual worker. Satisfactory training of individuals performing the work assures consistency of quality and knowledge of the requirements. Responsibilities for the methods in which work is to be performed are established in the procedures, work instructions and check lists. Line managers assure that personnel working under their supervision have the necessary training, resources and administrative controls needed to perform their tasks efficiently while maintaining and improving the quality of their work. Line managers accomplish this by planning, authorizing, and accomplishing work safely under controlled conditions in accordance with HMPTS plans, procedures, Principal Participant's SQAP and Procedures and the Federal, State, and other jurisdictional regulations and requirements. The line manager is also responsible for reviewing the work of their personnel and identifying areas needing improvement.

5.5.2 Principal Members Documents

Where required, specific HMPTS procedures, instructions, work processes, and check lists for work planning and control are prepared, reviewed and approved by technically competent personnel, selected by the division/section leader. These are contained in:

- Material Management Section Sealed Source Program and Procedures Manual, see Ref. 9, which contains MMS operational procedures for sealed sources.
- Nuclear Material Control and Accountability Program Manual, Volumes I through VII, see Ref. 10, which contains MMS operational procedures for controlled materials.
- Supply and Distribution Department Procedures Manual, Volumes 1 through 4, see Ref. 11.
- Hazardous Waste Management Manual of Procedures. See Ref. 12.
- Site 300 -- Site 300 Safety and Operations Manual, see Ref. 13.

5.5.3 Identification of Packaging and Transportation Processes

Work processes are established and implemented to identify, control, and maintain HMPTS activities and items. These processes include but are not limited to:

- Proper identification, control, and maintenance of HMPTS Program shipping containers. The Assurance Officer establishes these processes and assures that Principal Members implement necessary control into their QA plans.
- Proper identification and control of hazardous materials, hazardous substances, and hazardous wastes during their packaging operations, loading into containers, on-site transfers, and transporting and shipping them off-site.
- Where required, identification of HMPTS containers are controlled to assure traceability of individual container and components back to the supporting procurement documentation in accordance with appropriate regulations and procedures. The EPD Waste Certification Officer assures that a unique container identification process is implemented, where required.

5.5.4 Limited Shelf Life Items

Procedures and methods are established and implemented by the responsible Principal Members to identify and control items which become unfit for use after the specified shelf life.

5.5.5 Container Handling, Storage, and Shipping

Where required, HMPTS Principal Members establish and implement processes, special protective measures, and procedures to control handling, storage, transfer, cleaning, and preservation of HMPTS containers to prevent damage, loss, or deterioration. Special protective measures are used to maintain an acceptable quality environment for items transferred on-site or shipped off-site. These processes are reviewed by the responsible appropriate QA representative.

5.5.6 Container Marking and Labeling

Marking and labeling of shipping containers is maintained throughout packaging, transfer, shipping, handling, and storage. Marking and labeling of containers for transportation shall provide information to identify items and provide instructions or special controls to preserve items' integrity in accordance with applicable regulations and requirements. See DOE Order 1540.1 (Ref. 16), and 49 CFR 171-179, 172.301, 172.400, (Ref. 33), and the ICAO/IATA regulations.

5.5.7 Calibration and Maintenance of Monitoring/Data Collecting Equipment

5.5.7.1 Calibration Control

Principal Members assure that their QA plans and procedures establish control of calibration, maintenance, and use of measuring and test equipment used for monitoring and data collection in the HMPTS operations.

5.5.7.2 Measurement Accuracy

Principal Members assure that their QA plans, procedures, work instructions, check lists, and data sheets designate that the monitoring and data collection equipment for HMPTS work is of an accuracy and type suitable for the intended use.

Accuracy requirements for the equipment shall be specified and also include proper requirement(s) for calibration certification. Specific equipment used shall be identified and documented as part of the monitoring and data collection process to assure traceability to calibration and maintenance controls for that equipment.

5.6 Design Control — Criterion 6

Design Control is not developed and does not apply, since most of the products used to package and transport hazardous materials, hazardous substances, and hazardous wastes are designed by approved suppliers and are manufactured in accordance with ANSI Design Standard or other DOE contractors and not by LLNL. The suppliers are required to design, produce, test, and certify these products according to the proper designs specified by Federal, State, and other regulations and requirements. In those rare cases, where specific product is required which is designed by the supplier or/and not included in the DOT/ANSI or DOE approved design, a design review by LLNL based on the technical requirements and developed in accordance with the design process guidelines in the Mechanical Engineering Design Practices manual M-256, Section 2 “Design Reviews”, will be performed.

5.7 Container Procurement — Criterion 7

All procured containers, used by LLNL for the off-site transportation of hazardous materials, shall be processed through the HMPTS Assurance Office. Procurement is initiated by a requisition and processed and released by the HMPTS Assurance Officer for purchase from an approved supplier, by the HMPTS Procurement representative. This procurement process is established and implemented for HMPTS Program containers to assure that LLNL purchased containers, related items, and services meet and, when required, are certified to meet, established requirements and that they will perform as expected. This process assures that:

- Laboratory requisitions for containers which are to be used for off-site shipment of hazardous materials, hazardous substances, and hazardous wastes are prepared and processed through the HMPTS Assurance Office for review and approval. This review is for concurrence and to verify the inclusion of applicable quality requirements. All Laboratory requests for container for hazardous materials, hazardous substances, and hazardous wastes is centralized, consolidated, administered, and purchased by the HMPTS Committee Procurement representative.
- Laboratory packaging and container requirements are standardized and commensurate with the scope, complexity, risk, and importance of the hazardous materials, hazardous substances, and hazardous wastes to be packaged. Appropriate requirements are included on the purchase documents.
- Applicable technical and administrative requirements, such as specifications, codes, standards, and if required, additional tests, and inspections are invoked on the procurement documents.
- Container receiving inspection is performed in accordance with Receiving Inspection Procedure QP 8.1.

5.7.1 Container Supplier Qualification

Prospective HMPTS container suppliers are surveyed and monitored to determine if their technical and quality capabilities are acceptable and to assure that only qualified suppliers are selected. Container suppliers are assessed by a qualified LLNL QA representative in accordance with Supplier Survey Procedure, QP 7.1. When affirmed by the HMPTS Assurance Office, suppliers who are approved by the DOE Supplier Quality Information Group (SQIG) or who are certified and registered under the ISO 9000 Registrar Accreditation Board (RAB) or other recognized authority, may be included as an approved supplier after review of the survey data or upon receipt of a copy of the ISO Certificate which includes the registration number.

5.8 Inspection and Acceptance Testing — Criterion 8

5.8.1 Inspection and Test Process

The independent and documented container inspections and tests are performed in accordance with planned written procedures during the containers Laboratory life cycle. This includes all inspections and tests as required to be performed by this QAP and supporting procedures and by the Principal Members SQAP and procedures. For stored containers, Principal Members operations establish a container maintenance program to assure that containers remain in an acceptable shipping condition. Procedures will be established to prevent the inadvertent use of deficient shipping packages. The level of inspection and degree of independence of inspection personnel shall be based on risk and complexity. Written procedures shall identify container packaging and transportation processes to be inspected and tested, inspection and test techniques, characteristics and processes to be inspected or tested, hold points if needed, acceptance criteria, and the organization responsible for performing inspection or test. Properly calibrated and maintained measuring and test equipment is used for acceptance, when required. Items requiring rework or repair are re-inspected and if needed, re-tested for compliance before release. Repairs when required, are performed in accordance with approved procedures. Those identified as “use as is” must be approved by the HMPTS Assurance Office or the appropriate QA representative.

5.8.2 HMPTS Container Supplier Inspection and Testing

New HMPTS shipping containers are purchased from approved suppliers who perform inspections and tests required by established Federal, State, and other regulations and requirements. These tests are performed and certified, by the supplier or by an independent third party, to be in compliance with the applicable regulations. These certification(s) will remain on file at the supplier or if requested on the purchase order, copies will be forwarded with the shipment and filed in accordance with the receiving inspection procedure.

5.8.3 HMPTS Measuring and Test Equipment Process

A documented calibration program is maintained for all measuring instruments and test equipment employed in the HMPTS health and safety measurements and the container acceptance processes, by the Materials Management Section, Hazardous Control Group, and Mechanical Engineering Instrument Repair and Calibration Lab. This program identifies the types of equipment to be calibrated, frequency of calibration, the label to be applied, and that calibration is certified to be performed with equipment or standards traceable to a recognized national standards laboratory. The calibration is to be performed in accordance with the original equipment manufacturers

documentation or specific written procedures and may be performed by a qualified, approved supplier specializing in calibration or by qualified lab personnel. A documented record system and recall system are established to assure timely calibration and maintenance. Measuring devices and test equipment found out-of-calibration or out-of-tolerance shall be tagged or segregated and not used until successfully re-calibrated. The HMPTS Assurance Office reviews, determines, and records the acceptability of containers or packaging and transportation processes measured, inspected, or tested with an out-of-tolerance device, when notified by the calibration group..

5.9 Management Assessment — Criteria 9

In accordance with LLNL senior management requirements, the HMPTS Committee periodically evaluates the degree to which the management infrastructure and resources for which they are responsible are properly focused on achieving the mission objectives assigned. These assessments focus on how effectively human and material resources are being utilized with respect to the assigned mission objectives and that appropriate goals are being defined for improving performance. An effective assessment is defined as one that evaluates the state of the workers knowledge, the atmosphere for improvement, the level of mutual confidence and collaboration among workers, the adequacy of human and material resources, and the effectiveness of the implementation of the HMPTS 10 QA Criteria and applicable DOE Orders. The results of these assessments are reported to the appropriate level of management.

The HMPTS Committee shall establish and execute a management assessment schedule for the HMPTS QAP. Planned and periodic management assessments of the HMPTS QAP, and QA procedures, Principal Participant's SQAPs, and procedures shall be implemented as a way to improve quality. These evaluations are performed in accordance with documented assessment procedures by a technically knowledgeable assessment team, resulting in a report of findings and acceptance of implemented corrective actions. The assessment frequency shall be based on the importance and risk of the participant's work in achieving the HMPTS Program objective. Areas identified during assessments as deficient will be reassessed during the next scheduled appraisal to determine if the corrective actions implemented are effective and prevent recurrence.

Management assessments shall focus on how well the integrated HMPTS Program is working and shall identify management problems that hinder the HMPTS Program from achieving its objectives in accordance with Environment, Safety, Health, and Quality requirements.

The HMPTS internal assessment is described in HMPTS QA Procedure QP 9.1

5.10 Independent Assessment — Criteria 10

The HMPTS Committee Chairperson has the primary responsibility to assure that periodic Independent Program Assessments (IPA) are properly and satisfactorily conducted, by a technically knowledgeable independent organization, possibly from another institution, to assess how effectively the LLNL HMPTS 10 QA Criteria and applicable DOE Orders are implemented. The schedule, scope, and purpose of each assessment shall be mutually agreed upon in advance of each assessment and shall be based on documented criteria. It shall focus on improving processes by emphasizing line organization's achievement of quality. Written findings are submitted to the HMPTS Committee Chairperson, within a mutually agreed upon time. Assessment results shall be documented, tracked, and resolved by management having responsibility in the area(s) that were assessed as deficient. Follow up review of deficient areas shall continue until corrective actions are completed and satisfactorily closed out and signed as such by the HMPTS Assurance Manager and forwarded to the committee chairperson for his signature signifying approval. As a minimum, a

program assessment shall be performed at intervals such that the complete system is assessed at least once every three years for the complete HMPTS QA Criteria. Deficiencies, identified during the independent assessment, will be re-examined during the following independent assessment to assure that corrective actions have been implemented and are effective in preventing problem recurrence.

The HMPTS independent assessment is described in a “Memorandum Of Understanding” between Lawrence Livermore National Laboratory and Los Alamos National Laboratory, see Appendix I.

6.0 DOE Orders and HMPTS

DOE Orders prescribe a wide variety of management systems, and there is no single DOE Order that defines how to integrate these requirements and other Laboratory requirements into a total management system. The 10 HMPTS QA Criteria are used as QA requirements (see section 5) and as functional categories that orchestrate and integrate DOE Orders and other Laboratory policies into a total management system for achieving the HMPTS mission as outlined in the charter. As such, the HMPTS Chairperson does not interpret DOE Order 5700.6C as requiring the development of duplicate or redundant management systems when the requirements of other DOE Orders meet the requirements of one or more of the HMPTS 10 QA Criteria.

References

1. LLNL “On-site Hazardous Materials Packaging and Transportation Safety Manual”, UCRL-MA-108269
2. LLNL Materials Management “QA Plan for Hazardous Material Packaging and Transportation,” Manual M-078-91.
3. LLNL Hazardous Waste Management “QA Plan,” Manual M-078-92.
4. LLNL Materials Distribution “QA Plan for Hazardous Material Packaging and Transportation,” Manual M-078-93.
5. LLNL “Health and Safety Manual,” M-010.
6. LLNL “Training Program Manual,” UCRL-MA-106166.
7. LLNL “Quality Assurance Manual,” M-078.
8. LLNL Material Management Section “Sealed Source Program and Procedures Manual.”
9. LLNL “Nuclear Material Control and Accountability Program Manual,” Volumes I - VII.
10. LLNL Services and Distribution Department “Procedures Manual,” Volumes 1 - 4.
11. Hazardous Waste Management Manuals of Procedures.
12. LLNL “Site 300 Safety and Operations Manual.”
13. DOE Order 1540.1, “Materials Transportation and Traffic Management;” C001; C002; and C003.
14. DOE Order 1540.2, “Hazardous Material Packaging for Transport - Administrative Procedures.”
15. DOE Order 1540.3, “Base Technology for Radioactive Material Transportation Packaging Systems.”
16. DOE Order 1324.2A, “Records Disposition.”
17. DOE Order 232.1, “Occurrence Reporting and Processing of Operations Information.”
18. DOE Order 5480.3, “Safety Requirements for the Packaging and Transportation of Hazardous Materials, Hazardous Substances, and Hazardous Wastes,” .
19. DOE Order 5480.4, “Environmental Protection, Safety, and Health Protection Standards,” 05-15-84. which specifies the application of mandatory environmental protection, safety, and health protection (ES&H) standards to DOE operations.
20. DOE Order 5700.6C, “Quality Assurance.”
21. DOE Resource Guide (DRAFT), “Performance-Oriented Packaging for Hazardous Material.”

22. TITLE 10 CFR Part 71 Energy, "Packaging and Shipping of Radioactive Material."
23. TITLE 29 CFR, OSHA Regulations and Health Hazards Communication.
24. TITLE 40 CFR Parts 260-265, EPA Regulations/RCRA.
25. TITLE 40 CFR Parts 761, EPA Regulations/TOSCA
26. TITLE 49 CFR Parts 100-199 DOT Hazardous Material Regulations.
27. ANSI N14.5, "American National Standard for Leakage Tests on Packages for Shipment of Radioactive Materials."
28. ASME NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities."
29. International Atomic Energy Agency (IAEA) Safety Series No. 6, "Regulations for the Safe Shipping of Radioactive Material," and Supplement.
30. LLNL "TRU Waste Program Certification and Quality Assurance Plan," M-078-121.